

EXHIBIT F

1 - - -
2 :SUPERIOR COURT OF
:NEW JERSEY
3 IN RE: :LAW DIVISION -
PELVIC MESH/GYNECARE :ATLANTIC COUNTY
4 LITIGATION :
:MASTER CASE 6341-10
5 :
:CASE NO. 291 CT

9 March 14, 2012

	GOLKOW TECHNOLOGIES, INC.
24	877.370.3377 ph 917.951.5672 fax deps@golkow.com

Confidential - Subject to Stipulation and Order of Confidentiality

1 A. Well, I don't know about believing
2 it, but they need to read it and begin a discussion
3 with their physicians. I can't --

4 Q. Does it say anywhere in the patient
5 brochure, in big, set-off letters so that the
6 patient could not miss it, please understand, you're
7 not expected to rely on this document. It's just
8 supposed to be a jumping off point for your
9 discussion with your physician? Is there anything
10 like that?

11 MR. GAGE: Objection.

12 THE WITNESS: I can't recall, but I
13 have to believe in there that there is language to
14 say, discuss with your physician.

15 MR. SLATER: Move to strike after "I
16 can't recall."

17 BY MR. SLATER:

18 Q. Did you expect patients to think that
19 what was written in the Prolift® patient brochure
20 was true?

21 A. Yes.

22 Q. Did you expect patients to rely on
23 Ethicon to tell them the truth about the Prolift®
24 procedure in the patient brochure that was dedicated
25 to the Prolift®?

Confidential - Subject to Stipulation and Order of Confidentiality

1 A. As best we knew at the time it was
2 created, yes.

3 Q. So Ethicon expected that when a
4 patient would read the patient brochure, they would
5 believe what they were reading. Right?

6 A. Again, I can't speak for their
7 belief, but I believe it should be a body of
8 information that you then take to your doctor to
9 talk about.

10 MR. SLATER: Move to strike.

11 BY MR. SLATER:

12 Q. You knew that there were patients who
13 would read the patient brochure for the Prolift® and
14 rely on Ethicon's statements to them about the
15 benefits and risks of the procedure as part of their
16 decision about whether or not to let a surgeon put a
17 Prolift® in their body. Right?

18 MR. GAGE: Objection.

19 THE WITNESS: As part of that, yes.

20 BY MR. SLATER:

21 Q. And nowhere in that patient brochure
22 are patients told that they can suffer pain as a
23 result of the Prolift®. Right?

24 MR. GAGE: Objection.

25 THE WITNESS: I'd have to look at the

Confidential - Subject to Stipulation and Order of Confidentiality

1 director in Ethicon, you did not expect physicians
2 to rely upon the IFU for the Prolift® as an accurate
3 disclosure of the risks associated with the Prolift®
4 system?

5 MR. GAGE: Objection.

6 THE WITNESS: No. I think what I
7 said is I didn't -- they shouldn't depend on it as
8 the sole source of their information regarding the
9 Prolift® system.

10 BY MR. SLATER:

11 Q. My question is this: Did you expect
12 surgeons who were considering using the Prolift® to
13 rely upon the Prolift® IFU to accurately disclose
14 the risks associated with the use of the Prolift®
15 system?

16 MR. GAGE: Objection.

17 THE WITNESS: We should accurately
18 represent what we knew to be risks at the time, yes.

19 BY MR. SLATER:

20 Q. You knew that was required by federal
21 law. Right?

22 MR. GAGE: Objection.

23 BY MR. SLATER:

24 Q. By the FDA. Right?

25 MR. GAGE: Objection.

Confidential - Subject to Stipulation and Order of Confidentiality

1 THE WITNESS: Actually, I don't know
2 whether the FDA -- that is a regulatory decision.

3 BY MR. SLATER:

4 Q. And you felt that was your obligation
5 to physicians so they would know what the potential
6 adverse reactions were if they used that product.
7 Right?

8 MR. GAGE: Objection.

9 THE WITNESS: To the best of our
10 knowledge at the time, yes.

11 BY MR. SLATER:

12 Q. And if Ethicon had knowledge of an
13 adverse reaction and did not include it in the
14 Prolift® IFU, then the IFU would be deficient to
15 that extent. Right?

16 MR. GAGE: Objection.

17 THE WITNESS: No, that's not true.

18 BY MR. SLATER:

19 Q. Okay.

20 A. Because --

21 Q. So let me understand this.

22 MR. GAGE: The witness would like to
23 finish his answer.

24 MR. SLATER: He just said no. That's
25 all I was asking.

Confidential - Subject to Stipulation and Order of Confidentiality

1 Q. Well, I'm asking you, based on your
2 participation in the process at Ethicon, would that
3 be incorrect?

4 MR. GAGE: Objection.

5 THE WITNESS: I don't remember ever
6 being asked to give the -- a final decision about
7 adverse events being put in an IFU.

8 BY MR. SLATER:

9 Q. Let me understand this. Ethicon
10 understood it was expected to put all of the adverse
11 events into the IFU. However, if Ethicon failed to
12 list -- I'm going to ask the question differently.

13 If Ethicon determined an adverse
14 reaction to be material, meaning it doesn't just
15 happen, you know, so infrequently that you don't
16 have to consider it but it happens enough that you
17 can actually put a percentage on it --

18 A. Well --

19 MR. GAGE: Let him finish his
20 question.

21 BY MR. SLATER:

22 Q. Let me ask you this.

23 How would you define a complication
24 to be material enough that it would need to be
25 listed in the IFU? How did you define that as

Confidential - Subject to Stipulation and Order of Confidentiality

1 medical director?

2 A. Well, it would either need to have a
3 frequency or a severity that had some implication
4 for a risk/benefit ratio.

5 Q. Okay.

6 If a complication met that standard,
7 it needed to be called out in the IFU. Right?

8 A. Yes.

9 Q. And if it was not -- rephrase.

10 And if a complication that met that
11 standard was not included in the IFU, the IFU would
12 be deficient by definition. Correct?

13 MR. GAGE: Objection.

14 THE WITNESS: I think it has to be
15 based on the information you have at the time the
16 IFU is created, so it will always evolve.

17 BY MR. SLATER:

18 Q. The information Ethicon had about the
19 complications and risks from the Prolift® evolved
20 over the years. Right?

21 A. Yes.

22 Q. That evolution was actually fairly
23 significant as more and more procedures were done
24 and Ethicon saw more clinical studies. Right?

25 MR. GAGE: Objection.